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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,625	08/07/2001	Chad A. Mirkin	00-713-B1	2286

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EXAMINER

RILEY, JEZIA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,625

Applicant(s)

MIRKIN ET AL.

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-105 is/are pending in the application.
- 4a) Of the above claim(s) 1,25-28,33-41 and 44-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-24,29-32,42 and 43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-105 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traverse of group II in Paper No. 10, filed on 12/20/02, is acknowledged. The traversal is on the ground(s) that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between the inventions of groups I-XX. This is not found persuasive because the invention of group II is directed to a method using two types of nanoparticles as opposed to the other methods. Therefore if all the groups were searched together it will impose a serious burden on the examiner. The requirement is still deemed proper and is therefore made FINAL.

2. The disclosure is objected to because of the following informalities: The continuation data in the specification are incomplete.

If applicant desires priority under 35 U.S.C. § 120 based upon a parent application, specific reference to the parent application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. Status of the parent application (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "Patent No." should follow the filing date of the parent application. If a parent application has become abandoned, the expression "abandoned" should follow the filing date of the parent application. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 2, 3-24, 29-32, 42, 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Yguerabide et al. (6,214,560).

Yguerabide et al. discloses a method of light illumination and detection named "DLASLPD" (direct light angled for scattered light only from particle detected) disclose an analyte assay using gold particulate label for specific detection of one or more analytes in a sample. One or more analytes in a sample can be detected and measured by detection and/or measurement of one or more of the specific light scattering properties of metal-like particles. (Summary of the Invention). For example, a certain nucleic acid analyte is composed of about 100 nucleic acid bases and is present in a sample. The sample is prepared so that this nucleic acid is in a single stranded form. Then two or more unique single-stranded "probe" nucleic acid sequences are added to the sample where these different probes bind to different regions of the target strand. Each of these probes has attached to one or more particles (col. 74). Further, the particles can form different types of aggregates that can be detected visually or instrumentally in a microscope or through macroscopic observation or measurements without having to separate free from analyte bound particles. The type of

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aggregates formed depends on the size of the cross-linking agent or agents and their valency and on the type of binding agent attached to the particle. Aggregates can range from two particles to many. The method can be used in a multi-analyte detection in the microarray format. For many years, metal particles including gold and silver have been used as both contrast enhancement agents or light absorption labels in many different types of analytic and/or diagnostic applications. The great majority of these applications fall under the category of cytoimmunochemistry studies which have used gold or silver enhanced gold particles as markers to study structural aspects of cellular, subcellular, or tissue organization. In these studies, metal particles are usually detected and localized by electron microscopy, including scanning, transmission, and BEI (backscattered electron imaging). These methods take advantage of the electron dense nature of metals or the high atomic number of metals to facilitate the detection of the gold particles by virtue of the large numbers of secondary and backscattered electrons generated by the dense metal. For example, silver-enhancement of colloidal gold particles (20nm) bound to immunoglobulin enhanced the sensitivity, efficiency, and accuracy of antigen detectability in the light microscope. Yguerabide et al. has also determined the following: (1) one or more analytes in a sample can be detected and measured by detection and/or measurement of one or more of the specific light scattering properties of metal-like particles. These light scattering properties include the intensity, wavelength, color, polarization, angular dependence, and the RIFSLIW (rotational individual fluctuations in the scattered light intensity and/or wavelengths) of the scattered light. One or more of these properties of particle scattered light can be

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used to provide information regarding the analytes in the sample; (2) by varying the size, and/or shape and/or composition of a metal-like particle in various combinations, one or more of the light scattering properties can be adjusted to generate more easily detectable and measurable light scattering signals; (3) illumination and detection of the metal-like particles of certain size, shape, and composition with DLASLPD provides a highly sensitive and easy to use method to detect and measure metal-like particles by their light scattering properties. The method provides for single particle detection with easy to use and inexpensive apparatus means; (4) the DLASLPD methods can be used with particle counting and/or integrated light intensity measurements to provide for detection and measurement of the particles across wide concentration ranges; (5) the use of refractive index enhancement methods provides for enhancement of a particle's light scattering properties, and/or decreases in non-specific light background; (6) the use of DLASLPD video contrast enhancement methods can provide for more sensitive detection in many different types of samples and diagnostic assay formats; (7) for sensitive detection of analytes in a small solid-phase area such as commonly used in microarray and array chip formats, certain types of metal-like particles are more preferred to use than others. Metal-like particles in microarray and array chip formats can be most easily and inexpensively detected by using DLASLPD methods and (8) useful apparatus and particle types for specific test kits can be constructed. These different test kits, and associated apparatus are useful for applications to consumer use, portable field use, point of care applications such as doctor's offices, clinics, emergency rooms and the like, research laboratories, and centralized high throughput testing. The

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above aspects of the provide for detection of one or more analytes in many different types of samples and diagnostic assay formats.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-24, 29-32, 42 and 43 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Yguerabide et al. (6,214,560).

Yguerabide et al. disclose an analyte assay using gold particulate label for specific detection of one or more analytes in a sample. As discussed above.

The claims have added functions which the prior art has not analyzed such as the contacting conditions; but given the above 102 rejection analysis substantiating the basic characterization of the composition of the invention being the same as the reference, these added characteristics are presumed to be inherent in the prior art composition.

As it is pointed in *In re Fitzgerald* (205 USPQ), page 594, 2nd col., 1st full paragraph, supports the shifting of the burden of proof to the applicant that the instantly claimed invention is novel and unobvious over the prior art. Since both the prior art and the instant application prepare and use composition which appeared to be identical for hybridization assays. The prior art therefore suggests that the composition therein disclosed are effective in such assays therefore suggesting the instant application under 35 U.S.C. § 103(a).


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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

February 3, 2003


JEZIA RILEY
PRIMARY EXAMINER